

INTERNATIONAL STANDARD

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Quality management and quality assurance standards —

Part 1: Guidelines for selection and use

*Normes pour le management de la qualité et l'assurance de la qualité —
Partie 1: Lignes directrices pour leur sélection et utilisation*



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9000-1 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

The first edition of ISO 9000-1 cancels and replaces ISO 9000:1987. ISO/TC 176 adopted in 1990 a strategy for revision of the ISO 9000 series originally published in 1987. This is the first revision. This part of ISO 9000, which has the role of road map for the series, has been expanded substantially.

ISO 9000 consists of the following parts, under the general title *Quality management and quality assurance standards*:

- *Part 1: Guidelines for selection and use*
- *Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003*
- *Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*
- *Part 4: Guide to dependability programme management*

Annex A forms an integral part of this part of ISO 9000. Annexes B, C, D and E are for information only.

Introduction

Organizations — industrial, commercial or governmental — supply products intended to satisfy customers' needs and/or requirements. Increased global competition has led to increasingly more stringent customer expectations with regard to quality. To be competitive and to maintain good economic performance, organizations/suppliers need to employ increasingly effective and efficient systems. Such systems should result in continual improvements in quality and increased satisfaction of the organization's customers and other stakeholders (employees, owners, subsuppliers, society).

Customer requirements often are incorporated in “specifications”. However, specifications may not in themselves guarantee that a customer's requirements will be met consistently, if there are any deficiencies in the organizational system to supply and support the product. Consequently, these concerns have led to the development of quality system standards and guidelines that complement relevant product requirements given in the technical specifications. The International Standards in the ISO 9000 family are intended to provide a generic core of quality system standards applicable to a broad range of industry and economic sectors (clause 7).

The management system of an organization is influenced by the objectives of the organization, by its products and by the practices specific to the organization and, therefore, quality systems also vary from one organization to another. A major purpose of quality management is to improve the systems and processes so that continual improvement of quality can be achieved.

This part of ISO 9000, which has the role of road map for the ISO 9000 family, has been expanded substantially. In particular, it contains guidance concepts not included in the 1987 version. These additional concepts

- are needed for effective understanding and current application of the ISO 9000 family, and
- are planned for complete integration into the architecture and content of future revisions of the ISO 9000 family.

In revision of the ISO 9000 family, there are no major changes in the architectures of ISO 9001, ISO 9002, ISO 9003 and ISO 9004. (However, ISO 9003 does contain additional clauses compared to the 1987 version.) Each of these International Standards has had small-scale changes. These changes move toward future revisions to meet better the needs of users.

This part of ISO 9000 and all other International Standards in the ISO 9000 family are independent of any specific industry or economic sector. Collectively they provide guidance for quality management and general requirements for quality assurance.

The International Standards in the ISO 9000 family describe what elements quality systems should encompass but not how a specific

organization implements these elements. It is not the purpose of these International Standards to enforce uniformity of quality systems. Needs of organizations vary. The design and implementation of a quality system must necessarily be influenced by the particular objectives, products and processes, and specific practices of the organization.

This part of ISO 9000 clarifies the principal quality-related concepts contained within the quality management and quality assurance International Standards generated by ISO/TC 176 and provides guidance on their selection and use.

Quality management and quality assurance standards —

Part 1: Guidelines for selection and use

1 Scope

This part of ISO 9000

- a) clarifies principal quality-related concepts and the distinctions and interrelationships among them;
- b) provides guidance for the selection and use of the ISO 9000 family of International Standards on quality management and quality assurance.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 9000. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9000 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary*.

3 Definitions

This revision of ISO 9000, ISO 9001, ISO 9002, ISO 9003 and ISO 9004 has improved the harmonization of terminology for organizations in the supply chain. Table 1 shows the supply chain terminology used in these International Standards.

The usage of all of these terms conforms with their formal definitions in ISO 8402. The remaining differences in terminology in table 1 reflect, in part, a desire to maintain historical continuity with usage in the 1987 edition of these International Standards.

NOTES

1 In all these International Standards, the grammatical format of the guidance or requirements text is addressed to the organization in its role as a supplier of products (the third column of table 1).

2 In the ISO 9000 row of table 1, the use of "subsupplier" emphasizes the supply chain relationship of the three organizational units, using the self-defining term in relation to "supplier". Where appropriate, especially in discussing quality management situations, the term "organization" is used rather than "supplier".

3 In the ISO 9001, ISO 9002 and ISO 9003 rows of table 1, the use of "subcontractor" reflects the fact that, in an external quality assurance context, the relevant relationship often is (explicitly or implicitly) contractual.

4 In the ISO 9004 row of table 1, the use of "organization" reflects the fact that quality management guidance is applicable to any organizational unit, irrespective of the categories of products it may supply, or whether it is a free-standing unit or part of a larger organization.

For the purposes of this part of ISO 9000, the definitions given in ISO 8402, together with the following definitions, apply.

NOTE 5 For the convenience of users of this part of ISO 9000, some relevant definitions from ISO 8402 are contained in annex A.

Table 1 — Relationships of organizations in the supply chain

ISO 9000-1	Subsupplier	——>	supplier or organization	——>	customer
ISO 9001, ISO 9002, ISO 9003	Subcontractor	——>	supplier	——>	customer
ISO 9004-1	Subcontractor	——>	organization	——>	customer

3.1 hardware: Tangible, discrete product with distinctive form.

NOTE 6 Hardware normally consists of manufactured, constructed or fabricated pieces, parts and/or assemblies.

3.2 software: An intellectual creation consisting of information expressed through supporting medium.

NOTES

7 Software can be in the form of concepts, transactions or procedures.

8 A computer program is a specific example of software.

3.3 processed material: Tangible product generated by transforming raw material into a desired state.

NOTES

9 The state of processed material can be liquid, gas, particulate material, ingot, filament or sheet.

10 Processed material is typically delivered in drums, bags, tanks, cylinders, cans, pipelines or rolls.

3.4 industry/economic sector: A grouping of suppliers whose offerings meet similar customer needs and/or whose customers are closely interrelated in the marketplace.

NOTES

11 Dual use of “industry sector” and “economic sector” recognizes that each term is used for the intended meaning in specific countries or languages.

12 Industry/economic sectors include administration, aerospace, banking, chemicals, construction, education, food, health care, leisure, insurance, mining, retailing, telecommunications, textiles, tourism, and so forth.

13 Industry/economic sectors apply to the global economy or a national economy.

3.5 stakeholder: An individual or group of individuals with a common interest in the performance of

the supplier organization and the environment in which it operates.

3.6 ISO 9000 family: All those International Standards produced by the technical committee ISO/TC 176.

NOTE 14 At present, the family comprises

- a) all the International Standards numbered ISO 9000 through to ISO 9004, including all parts of ISO 9000 and ISO 9004;
- b) all the International Standards numbered ISO 10001 through to 10020, including all parts; and
- c) ISO 8402.

4 Principal concepts

4.1 Key objectives and responsibilities for quality

An organization should:

- a) achieve, maintain and seek to improve continuously the quality of its products in relationship to the requirements for quality;
- b) improve the quality of its own operations, so as to meet continually all customers' and other stakeholders' stated and implied needs;
- c) provide confidence to its internal management and other employees that the requirements for quality are being fulfilled and maintained, and that quality improvement is taking place;
- d) provide confidence to the customers and other stakeholders that the requirements for quality are being, or will be, achieved in the delivered product;
- e) provide confidence that quality system requirements are fulfilled.

4.2 Stakeholders and their expectations

Every organization as a supplier has five principal groups of stakeholders: its customers, its employees, its owners, its subsuppliers and society.

The supplier should address the expectations and needs of all its stakeholders.

Supplier's stakeholders	Typical expectations or needs
Customers	Product quality
Employees	Career/work satisfaction
Owners	Investment performance
Subsuppliers	Continuing business opportunity
Society	Responsible stewardship

The International Standards in the ISO 9000 family focus their guidance and requirements on satisfying the customer.

The requirements of society, as one of the five stakeholders, are becoming more stringent world-wide. In addition, expectations and needs are becoming more explicit for considerations such as: workplace health and safety; protection of the environment (including conservation of energy and natural resources); and security. Recognizing that the ISO 9000 family of International Standards provides a widely used approach for management systems that can meet requirements for quality, these management principles can be useful for other concerns of society. Compatibility of the management system approach in these several areas can enhance the effectiveness of an organization. In the same manner that product and process technical specifications are separate from management systems requirements, the technical specifications in these other areas should be separately developed.

4.3 Distinguishing between quality system requirements and product requirements

The ISO 9000 family of International Standards makes a distinction between quality system requirements and product requirements. By means of this distinction, the ISO 9000 family applies to organizations providing products of all generic product categories, and to all product quality characteristics. The quality system requirements are complementary to the technical requirements of the product. The applicable technical specifications of the product (e.g. as set out in product standards) and technical specifications of the process are separate and distinct from the applicable ISO 9000 family requirements or guidance.

International Standards in the ISO 9000 family, both guidance and requirements, are written in terms of the quality system objectives to be satisfied. These International Standards do not prescribe how to achieve the objectives but leave that choice to the management of the organization.

4.4 Generic product categories

It is useful to identify four generic product categories (see clause 3 and annex A), as follows:

- a) hardware;
- b) software;
- c) processed materials;
- d) services.

These four generic product categories encompass all the kinds of product supplied by organizations. International Standards in the ISO 9000 family are applicable to all four generic product categories. The quality system requirements are essentially the same for all generic product categories, but the terminology and management system details and emphases may differ.

Two or more of the generic product categories usually are present in the marketplace offerings of any organization, whatever the industry/economic sector (see clause 3) in which the organization operates. For example, most organizations that supply hardware, software or processed materials have a service component to their offering. Customers (and other stakeholders) will look for value in each generic product category that is present in the offering.

Analytical instruments are examples where hardware (i.e. the instrument), software (for computing tasks within the instrument), processed materials (such as titrating solutions or reference materials) and services (such as training or maintenance servicing) might all be important features of the offering. A service organization such as a restaurant will have hardware, software and processed materials as well as service components.

4.5 Facets of quality

Four facets that are key contributions to product quality may be identified as follows.

a) **Quality due to definition of needs for the product**

The first facet is quality due to defining and updating the product, to meet marketplace requirements and opportunities.

b) **Quality due to product design**

The second facet is quality due to designing into the product the characteristics that enable it to meet marketplace requirements and opportunities, and to provide value to customers and other stakeholders. More precisely, quality due to product design is the product design features that influence the intended performance within a given grade, plus product design features that influence the robustness of product performance under variable conditions of production and use.

c) **Quality due to conformance to product design**

The third facet is quality due to maintaining day-to-day consistency in conforming to product design and in providing the designed characteristics and values for customers and other stakeholders.

d) **Quality due to product support**

The fourth facet is quality due to furnishing support throughout the product life cycle, as needed, to provide the designed characteristics and values for customers and other stakeholders.

For some products, the important quality characteristics include dependability characteristics. Dependability (i.e. reliability, maintainability and availability) may be influenced by all four facets of product quality.

A goal of the guidance and requirements of the International Standards in the ISO 9000 family is to meet the needs for all four facets of product quality. Some facets of quality may be specifically important, for example, in contractual situations, but, in general, all facets contribute to the quality of the product. The ISO 9000 family explicitly provides generic quality management guidance and external quality assurance requirements on facets a), b), c) and d).

When considering the complete product offering, the customer will bear in mind additional factors. These include the following.

- The supplier's market status and strategy: if the supplier has an established and reputable marketplace status and/or a strategy that is achieving a

satisfactory market share, the customer is likely to place higher value on the supplier's offering.

- The supplier's financial status and strategy: if the supplier has an established and reputable financial status and/or a strategy that is improving financial performance, the customer is likely to place higher value on the supplier's offering.
- The supplier's human resources status and strategy: if the supplier has an established and reputable human resources status and/or a strategy that is developing improved skills, diversity and commitment in its human resources, the customer is likely to place higher value on the supplier's offering.

These additional factors are of vital importance in managing a supplier organization as a total enterprise.

NOTE 15 Product value involves both quality and price and, as such, price is not a facet of quality.

4.6 Concept of a process

The International Standards in the ISO 9000 family are founded upon the understanding that all work is accomplished by a process (see figure 1). Every process has inputs. The outputs are the results of the process. The outputs are products, tangible or intangible. The process itself is (or should be) a transformation that adds value. Every process involves people and/or other resources in some way. An output may be, for example, an invoice, computing software, liquid fuel, a clinical device, a banking service, or a final or intermediate product of any generic category. There are opportunities to make measurements on the inputs, at various places in the process, as well as on the outputs. As shown in figure 2, inputs and outputs are of several types.

Type	Examples
Product-related (solid lines in figure 2)	Raw materials Intermediate product Final product Sampled product
Information-related (dashed lines in figure 2)	Product requirements Product characteristics and status information Support-function communications Feedback on product performance and needs Measurement data from sampled product

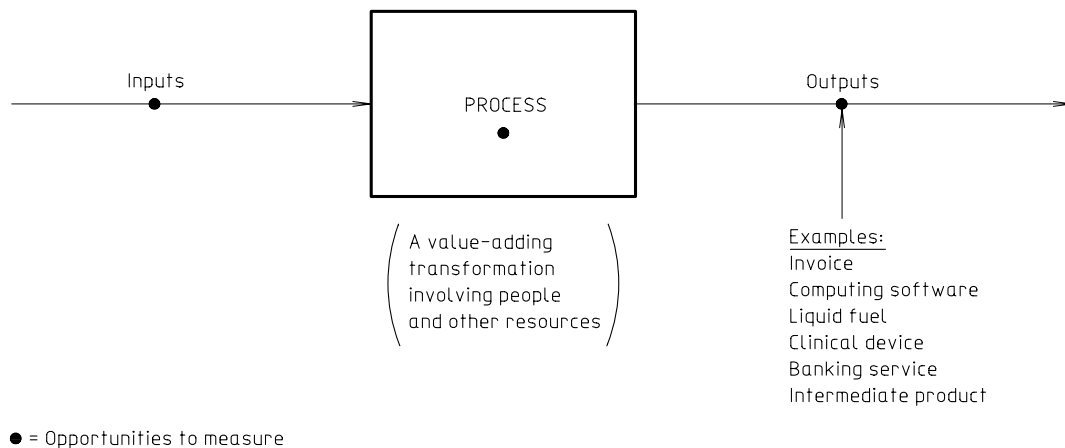


Figure 1 — All work is accomplished by a process

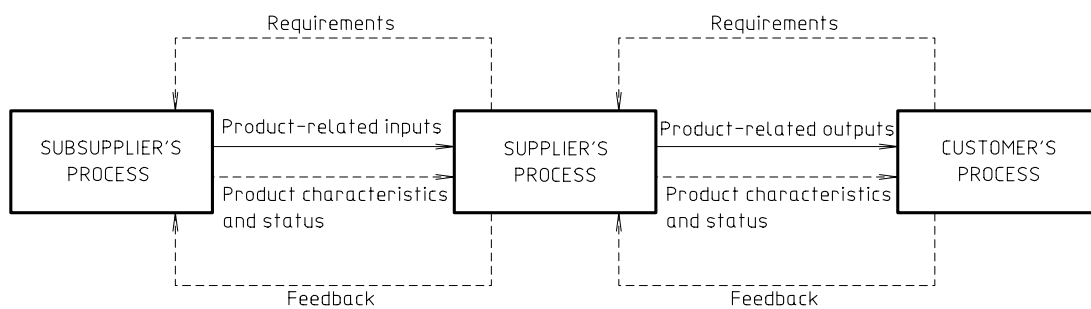


Figure 2 — Supply chain relationship of processes, with product-related and information-related flow

Figure 2 shows the supplier in a supply chain relationship to a subsupplier and a customer. In this supply chain structure, the various inputs and outputs need to flow in different directions, as illustrated in figure 2. It is emphasized that in this context "product" includes all four generic product categories.

Quality management is accomplished by managing the processes in the organization. It is necessary to manage a process in two senses:

- the structure and operation of the process itself within which the product or information flows; and
- the quality of the product or information flowing within the structure.

4.7 Network of processes in an organization

Every organization exists to accomplish value-adding work. The work is accomplished through a network

of processes. The structure of the network is not usually a simple sequential structure, but typically is quite complex.

In an organization there are many functions to be performed. They include production, product design, technology management, marketing, training, human resources management, strategic planning, delivery, invoicing and maintenance. Given the complexity of most organizations, it is important to highlight the main processes and to simplify and prioritize processes for quality management purposes.

An organization needs to identify, organize and manage its network of processes and interfaces. The organization creates, improves and provides consistent quality in its offerings through the network of processes. This is a fundamental conceptual basis for the ISO 9000 family. Processes and their interfaces should be subject to analysis and continuous improvement.

Problems tend to arise where people have to manage several processes and their interrelationships, particularly for large processes that may span several functions. To clarify interfaces, responsibilities and authorities, a process should have an owner as the person responsible. The quality of executive management's own processes, such as strategic planning, is especially important.

4.8 Quality system in relation to the network of processes

It is conventional to speak of a quality system as consisting of a number of elements. The quality system is carried out by means of processes, which exist both within and across functions. For a quality system to be effective, these processes and the associated responsibilities, authorities, procedures and resources should be defined and deployed in a consistent manner. A system is more than a sum of processes. To be effective, the quality system needs coordination and compatibility of its component processes, and definition of their interfaces.

4.9 Evaluating quality systems

4.9.1 General

When evaluating quality systems, there are three essential questions that have to be asked in relation to every process being evaluated, as follows.

- a) Are the processes defined and their procedures appropriately documented?
- b) Are the processes fully deployed and implemented as documented?
- c) Are the processes effective in providing the expected results?

The collective answers to these questions relating respectively to the approach, deployment and results, will determine the outcome of the evaluation. An evaluation of a quality system may vary in scope, and encompass a wide range of activities, some of which are discussed in 4.9.2 and 4.9.3.

4.9.2 Management review

One of the important activities that executive management of the supplier organization needs to carry out systematically is an evaluation of the status and adequacy of the quality system, including the quality policy, in relation to the expectations of the stakeholders. Management reviews usually take into account many additional factors beyond the require-

ments found in ISO 9001, ISO 9002 or ISO 9003. The results of internal audits and external audits are an important source of information. It is important that the outcome of the management review should lead to increased effectiveness and efficiency of the quality system.

4.9.3 Quality system audits

In evaluating the effectiveness of a quality system, audits are an important element. Audits may be conducted by, or on behalf of, the organization itself (first party), its customers (second parties) or independent bodies (third parties). The second or third party audit may provide an enhanced degree of objectivity from the customer's perspective.

First-party internal quality audits may be conducted by members of the organization or by other persons on behalf of the organization. These provide information for effective management review and corrective, preventive or improvement action.

Second-party quality audits may be conducted by customers of the organization, or by other persons on behalf of the customer where there is a contract or a series of contracts under consideration. These provide confidence in the supplier.

Third-party quality audits may be carried out by competent certification bodies to gain certification or registration, thereby providing confidence to a range of potential customers.

The basic requirements for quality systems are contained in ISO 9001, ISO 9002 and ISO 9003. Parts 1, 2 and 3 of ISO 10011 give guidance on auditing.

NOTE 16 A first-party audit is often called an "internal" audit, whereas second-party and third-party quality audits are often called "external" quality audits.

5 Roles of documentation

5.1 Value of documentation

In the context of the ISO 9000 family, the preparation and use of documentation is intended to be a dynamic high-value-adding activity. Appropriate documentation is essential for several critical roles:

- achieving required (product) quality;
- evaluating quality systems;
- quality improvement;
- maintaining the improvements.

5.2 Documentation and evaluation of quality systems

For auditing purposes, documentation of procedures is objective evidence that

- a process has been defined,
- the procedures are approved, and
- the procedures are under change control.

Only under these circumstances can internal or external audits provide a meaningful evaluation of the adequacy of both deployment and implementation.

5.3 Documentation as a support for quality improvement

Documentation is important for quality improvement. When procedures are documented, deployed and implemented, it is possible to determine with confidence how things are done currently and to measure current performance. Then reliable measurement of the effect of a change is enhanced. Moreover, documented standard operating procedures are essential for maintaining the gains from quality improvement activities.

5.4 Documentation and training

Maintaining consistency of the procedures that are deployed and implemented results from a combination of the documentation and the skills and training of personnel. In each situation an appropriate balance between the extent of documentation and the extent of skills and training should be sought, so as to keep documentation to a reasonable level that can be maintained at appropriate intervals. Quality system audits should be performed with this necessary balancing in mind.

6 Quality system situations

The ISO 9000 family is intended to be used in four situations:

- a) guidance for quality management;
- b) contractual, between first and second parties;
- c) second-party approval or registration; and
- d) third-party certification or registration.

The suppliers's organization should install and maintain a quality system designed to cover all the situ-

ations [among those listed under a), b), c) and d)] that the organization meets.

For situation a), this system will strengthen its own competitiveness to fulfil the requirements for product quality in a cost-effective way.

In situation b), the customer may be interested in certain elements of the supplier's quality system which affect the supplier's ability consistently to produce product to requirements, and the associated risks. The customer, therefore, contractually requires that certain quality system elements and processes, as appropriate, be part of the supplier's quality system, by specifying a particular quality assurance model.

In situation c), the supplier's quality system is assessed by the customer. The supplier may be given formal recognition of conformance with the standard.

In situation d), the supplier's quality system is evaluated by the certification body, and the supplier agrees to maintain the quality system for all customers unless otherwise specified in an individual contract. This type of quality system certification or registration often reduces the number and/or extent of quality system assessments by customers.

A single supplier often will be involved in situations of all types. The supplier may purchase some materials or components from standard inventory without contractual quality system requirements, and purchase others with contractual quality system requirements. The same supplier may sell some products in non-contractual situations, with or without customers expecting quality system certification, and may sell other products in contractual situations.

A supplier can elect to use the ISO 9000 family in either of two ways, which may be called "management motivated" and "stakeholder motivated", respectively. In either case, the supplier should initially consult this part of ISO 9000, the road map for the ISO 9000 family, to understand basic concepts and the types of standards available in the family.

The stakeholder-motivated approach is the predominant practice in many nations and industry/economic sectors. The increasing use of quality system certification/registration is a factor in the spread of this approach.

In the stakeholder-motivated approach, the supplier initially implements a quality system in response to immediate demands by customers or other stakeholders. The selected quality system conforms to the requirements of ISO 9001, ISO 9002 or ISO 9003, as applicable. The supplier's management must play a

significant leadership role in this approach, but the effort is driven by external stakeholders. Typically, the supplier finds that significant improvements in product quality, costs and internal operating results are obtained. At the same time, or later, the supplier may initiate a quality management effort to gain further improvements, building a more comprehensive quality system from the selected quality assurance model as a core building block.

In the management-motivated approach, the supplier's own management initiates the effort in anticipation of emerging marketplace needs and trends. In this route, ISO 9004-1 (and other applicable parts of ISO 9004) are used first, to guide a quality management approach to installing a quality system that will enhance the supplier's quality achievement. Subsequently, the supplier can use the applicable requirement standard, ISO 9001, ISO 9002 or ISO 9003, as the quality assurance model for demonstrating the adequacy of the quality system, possibly seeking certification in advance of any customer requirement as a preparatory measure.

The quality system implemented in this management-motivated approach will normally be more comprehensive and fruitful than the model used for demonstrating the adequacy of the quality system.

7 Selection and use of International Standards on quality

7.1 General

For quality management purposes, organizations should use the ISO 9000 family of International Standards in order to develop, implement and improve their quality system in both the management-motivated and stakeholder-motivated situations.

The ISO 9000 family contains two types of guidance standards. Application guidance for quality assurance purposes is provided by several parts of ISO 9000. Specialized application guidance for quality management purposes is provided by the parts of ISO 9004. These parts of ISO 9004 are not intended to be used to interpret the requirements of the quality assurance standards, however, they can provide useful references. Likewise, International Standards with num-

bers in the 10000 sequence may be used for reference.

Throughout the ISO 9000 family, emphasis is placed on the satisfaction of customers' needs, the establishment of functional responsibilities, and the importance of assessing (as far as possible) the potential risk and benefits. All these aspects should be considered in establishing and maintaining an effective quality system, and its continuous improvement.

Special attention should be paid to ISO 9004-1 which deals with quality management of any product (see 7.9) and applies to all generic product categories and all industry/economic sectors.

Using ISO 9004-1, the supplier should determine according to a specific situation the extent to which each quality system element is applicable and which specific methods and technologies are to be applied; appropriate parts of the ISO 9000 family give further guidance.

Subclauses 7.2 to 7.16 give guidance to enable organizations to select appropriate International Standards from the ISO 9000 family that would provide useful information for implementing and operating quality systems.

7.2 Selection and use

ISO 9000-1:1994, *Quality management and quality assurance standards — Part 1: Guidelines for selection and use*

Reference should be made to ISO 9000-1 by any organization which is contemplating the development and implementation of a quality system.

Increased global competition has led to increasingly more stringent customer expectations with regard to quality. To be competitive and sustain good economic performance, organizations/suppliers need to employ increasingly effective and efficient systems.

ISO 9000-1 clarifies the principal quality-related concepts and provides guidance for the selection and use of the ISO 9000 family for this purpose.

7.3 Application guidelines

ISO 9000-2:1993, *Quality management and quality assurance standards — Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003*

ISO 9000-2 should be selected when assistance is needed in the implementation and application of ISO 9001, ISO 9002 and ISO 9003 (see clause 8).

It provides guidance on the implementation of the clauses in the quality assurance standards and is particularly useful during the initial implementation.

7.4 Software

ISO 9000-3:1991, *Quality management and quality assurance standards — Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*

(ISO 9000-3 deals exclusively with computer software.)

Reference should be made to ISO 9000-3 by supplier organizations implementing a quality system in accordance with ISO 9001 for a software product or a product which includes a software element.

The process of development, supply and maintenance of software is different from that of most other types of industrial products in that there is no distinct manufacturing phase. Software does not “wear out” and, consequently, quality activities during the design phase are of paramount importance to the final quality of the product.

ISO 9000-3 sets out guidelines to facilitate the application of ISO 9001 in organizations developing, supplying and maintaining software, by suggesting appropriate controls and methods for this purpose.

7.5 Dependability

ISO 9000-4:1993, *Quality management and quality assurance standards — Part 4: Guide to dependability programme management*

ISO 9000-4 should be selected when the supplier needs to provide assurance of the dependability (i.e. reliability, maintainability and availability) characteristics of a product.

Society's increasing reliance upon services such as transportation, electricity, telecommunications and information services leads to higher customer requirements and expectations with regard to quality of service. The dependability of products used for such services is a major contributing factor to their quality of service.

ISO 9000-4 provides guidance on dependability programme management. It covers the essential features of a comprehensive dependability programme for the planning, organization, direction and control of

resources to produce products that will be reliable and maintainable.

7.6 Quality assurance: design, development, production, installation and servicing

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*

ISO 9001 should be selected and used when the need is to demonstrate the supplier's capability to control the processes for design as well as production of conforming product. The requirements specified are aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages from design through to servicing. ISO 9001 specifies a quality assurance model for this purpose.

7.7 Quality assurance: production, installation and servicing

ISO 9002:1994, *Quality systems — Model for quality assurance in production, installation and servicing*

ISO 9002 should be selected and used when the need is to demonstrate the supplier's capability to control the processes for production of conforming product. ISO 9002 specifies a quality assurance model for this purpose.

7.8 Quality assurance: final inspection and test

ISO 9003:1994, *Quality systems — Model for quality assurance in final inspection and test*

ISO 9003 should be selected and used when conformance to specified requirements is to be assured by the supplier solely at final inspection and test. ISO 9003 specifies a quality assurance model for this purpose.

7.9 Quality management

ISO 9004-1:1994, *Quality management and quality system elements — Part 1: Guidelines*

Reference should be made to ISO 9004-1 by any organization intending to develop and implement a quality system.

In order to meet its objectives, the organization should ensure that the technical, administrative and human factors affecting the quality of its products will be under control, whether hardware, software, processed materials or services.

ISO 9004-1 describes an extensive list of quality system elements pertinent to all phases and activities in the life cycle of a product to assist an organization to select and apply elements appropriate to its needs.

7.10 Services

ISO 9004-2:1991, *Quality management and quality system elements — Part 2: Guidelines for services*

Reference should be made to ISO 9004-2 by organizations that provide services or whose products include a service component.

The characteristics of a service can differ from those of other products and can include such aspects as personnel, waiting time, delivery time, hygiene, credibility and communication delivered directly to the final customer. Customer assessment, often very subjective, is the ultimate measure of the quality of a service.

ISO 9004-2 supplements the guidance of ISO 9004-1 with respect to products in the services category. It describes the concepts, principles and quality system elements which are applicable to all forms of service offerings.

7.11 Processed materials

ISO 9004-3:1993, *Quality management and quality system elements — Part 3: Guidelines for processed materials*

Reference should be made to ISO 9004-3 by organizations whose products (final or intermediate) are prepared by transformations, and which consist of solids, liquids, gases or combinations thereof (including particulate materials, ingots, filaments or sheet structures). Such products are typically delivered in bulk systems such as pipelines, drums, bags, tanks, cans or rolls.

By their nature, processed (bulk) materials present unique difficulties with regard to the verification of the product at important points in the production process. This increases the importance of the use of statistical sampling and evaluation procedures and their application to in-process controls and final product specifications.

ISO 9004-3 supplements the guidance of ISO 9004-1 with respect to products in the processed materials category.

7.12 Quality improvement

ISO 9004-4:1993, *Quality management and quality system elements — Part 4: Guidelines for quality improvement*

Reference should be made to ISO 9004-4 by any organization wishing to improve its effectiveness (whether or not it has implemented a formal quality system).

A constant goal of management of all functions and at all levels of an organization should be to strive for customer satisfaction and continuous quality improvement.

ISO 9004-4 describes fundamental concepts and principles, management guidelines and methodology (tools and techniques) for quality improvements.

7.13 Audits

ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing*

ISO 10011-1 should be selected when establishing, planning, carrying out and documenting audits of quality systems. It provides guidelines for verifying the existence and implementation of elements of a quality system, and for verifying the system's ability to achieve defined quality objectives.

7.14 Auditors

ISO 10011-2:1991, *Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors*

ISO 10011-2 should be selected when staff selection and training for quality systems auditors is needed.

It provides guidance on the qualification criteria for quality systems auditors. It contains guidance on the education, training, experience, personal attributes and management capabilities needed to carry out an audit.

7.15 Managing audits

ISO 10011-3:1991, *Guidelines for auditing quality systems — Part 3: Management of audit programmes*

ISO 10011-3 should be selected when planning the management of an audit programme. It provides basic guidelines for managing quality systems audit programmes. It is consistent with the other parts of ISO 10011.

7.16 Quality assurance for measurement

ISO 10012-1:1992, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment*

ISO 10012-1 should be selected when the product or process quality depends heavily on the ability to measure accurately. It specifies the main features of the confirmation system to be used for a supplier's measuring equipment. It contains the quality assurance requirements for a supplier's measurement equipment to ensure that measurements are made with the intended accuracy and consistency. It contains more detailed requirements than those found in ISO 9001, ISO 9002 and ISO 9003, and is presented with guidance for implementation.

8 Selection and use of International Standards for external quality assurance

8.1 General guidance

In second-party approval or registration [situations b) and c) in clause 6], the supplier and the other party should agree on which International Standard will be used as the basis for approval. The selection and application of a model for quality assurance appropriate to a given situation should provide benefits to both customer and supplier.

Examining the benefits, risks and costs for both parties will determine the extent and nature of reciprocal information and the measures each party should take to provide adequate confidence that the intended quality will be achieved. The supplier has the responsibility to select the model for subcontracts unless otherwise agreed with the customer.

In third-party certification/registration, the supplier and the certification body should agree on which International Standard will be used as the basis for certification/registration. The selected model should be adequate and not misleading from the point of view of the supplier's customers. For example, the role and character of design activities, if any, is especially important in selecting between ISO 9001 and ISO 9002. The selection and application of a model for quality assurance appropriate to a given situation should also support the supplier's objectives. Examining the scope of the supplier's activities which will be encompassed by the certificate will determine the extent and nature of reciprocal information and the measures each party should take to provide confidence that the certification is maintained in accordance with the requirements of the selected model.

8.2 Selection of model

8.2.1 Three models for quality assurance

As indicated in 7.6 to 7.8, in the three relevant International Standards, certain quality system elements have been grouped to form three distinct models suitable for the purpose of suppliers demonstrating their capabilities and for assessment of such supplier capability by external parties.

- a) ISO 9001: for use when conformance to specified requirements is to be assured by the supplier during design, development, production, installation and servicing.
- b) ISO 9002: for use when conformance to specified requirements is to be assured by the supplier during production, installation and servicing.

NOTE 17 ISO 9002 is identical to ISO 9001 except for the deletion of all quality system requirements for design control.

- c) ISO 9003: for use when conformance to specified requirements is to be assured by the supplier at final inspection and test.

In 4.6 to 4.8 and elsewhere, a process perspective is emphasized. The goal of the quality system is to fulfil the requirements for quality in the results from the supplier's processes. But the quality system requirements are directed toward the procedures for these processes. Therefore, specific quality system requirements in ISO 9001, ISO 9002 and ISO 9003 usually are phrased: "The supplier shall establish and maintain documented procedures..."

8.2.2 Selection

The scopes of the International Standards as summarized in 8.2.1 indicate how the choice should be made among ISO 9001, ISO 9002 or ISO 9003 consistent with the situations a), b), c) and d) in clause 6.

8.3 Demonstration of conformance to the selected model

The quality system elements should be documented and demonstrable in a manner consistent with the requirements of the selected model.

Demonstration of the quality system elements and their associated processes provides confidence on:

- a) adequacy of the quality system;

- b) capability to achieve product conformity with the specified requirements.

The responsibility for demonstrating the adequacy and effectiveness of the quality system lies with the supplier. However, the supplier may need to consider the expectations for demonstration to the relevant interested parties as described in clause 6 b), c) and d). These considerations may determine the means adopted to demonstrate conformance to the selected model. Methods may include:

- supplier's declaration of conformity;
- providing basic documented evidence;
- providing evidence of approvals or registrations by other customers;
- audit by the customer;
- audit by a third party;
- providing evidence of competent third-party certificates.

Any of these means or a combination of them may apply in situations b) and c) of clause 6. In the 6 d) situation, the last two means are applicable.

The nature and degree of demonstration may vary from one situation to another in accordance with such criteria as:

- a) the economics, uses and conditions of use of the product;
- b) the complexity and innovation required to design the product;
- c) the complexity and difficulty of producing the product;
- d) the ability to judge product quality on the basis of final inspection and test alone;
- e) the requirements of society regarding the product;
- f) the past performance of the supplier;
- g) the degree of partnership in the relationship with the customer.

8.4 Additional considerations in contractual situations

8.4.1 Tailoring and contractual elements

Experience has shown that with a small fixed number of International Standards available, it is possible in almost every given contractual situation to select one that will meet needs adequately. However, on occasions, certain quality system elements or sub-elements called for in the selected International Standard may be deleted and, on other occasions, elements or sub-elements may be added. Tailoring may also concern the degree of demonstration of quality system elements. If tailoring should prove necessary, it should be agreed between the customer and the supplier, and should be specified in the contract.

8.4.2 Review of contractual quality system elements

Both parties should review the proposed contract to be sure that they understand the quality system requirements and that the requirements are mutually acceptable considering the economics and risks in their respective situations.

8.4.3 Supplementary quality assurance requirements

There may be a need to specify supplementary requirements in the contract, such as statistical process control or systems requirements for safety-critical items.

8.4.4 Pre-contract assessment

Assessments of a supplier's quality system according to ISO 9001, ISO 9002 or ISO 9003 and, when appropriate, supplementary requirements often are utilized prior to a contract to determine the supplier's ability to satisfy the requirements. In many cases, assessments are performed directly by the customer.

8.4.5 Audits after award of the contract

Continuing demonstration of the supplier's quality system after award of the contract may be achieved by a series of quality audits conducted by the customer, the customer's agent, or an agreed third party.

Annex A

(normative)

Terms and definitions taken from ISO 8402:1994

A.1 quality: Totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.

NOTES

18 In a contractual environment, or in a regulated environment, such as the nuclear safety field, needs are specified, whereas in other environments, implied needs should be identified and defined.

19 In many instances, needs can change with time; this implies periodic review of requirements for quality.

20 Needs are usually translated into characteristics with specified criteria. Needs may include, for example, aspects of performance, usability, dependability (availability, reliability, maintainability), safety, environment, economics and aesthetics.

21 The term “quality” is not used as a single term to express a degree of excellence in a comparative sense, nor should it be used in a quantitative sense for technical evaluations. To express these meanings, a qualifying adjective should be used. For example, use can be made of the following terms:

- a) “relative quality” where entities are ranked on a relative basis in the degree of excellence or comparative sense (not to be confused with grade);
- b) “quality level” in a quantitative sense (as used in acceptance sampling) and “quality measure” where precise technical evaluations are carried out.

22 The achievement of satisfactory quality involves all stages of the quality loop as a whole. The contributions to quality of these various stages are sometimes identified separately for emphasis; for example, quality due to definition of needs, quality due to product design, quality due to conformance, quality due to product support throughout its lifetime.

23 In some references, quality is referred to as “fitness for use” or “fitness for purpose” or “customer satisfaction” or “conformance to the requirements”. These represent only certain facets of quality, as defined above.

A.2 quality policy: Overall intentions and direction of an organization with regard to quality, as formally expressed by top management.

NOTE 24 The quality policy forms one element of the corporate policy and is authorized by top management.

A.3 quality management: All activities of the overall management function that determine the quality policy, objectives and responsibilities, and implement them by means such as quality planning, quality control, quality assurance and quality improvement within the quality system.

NOTES

25 Quality management is the responsibility of all levels of management but must be led by top management. Its implementation involves all members of the organization.

26 In quality management, consideration is given to economic aspects.

A.4 quality system: Organizational structure, procedures, processes and resources needed to implement quality management.

NOTES

27 The quality system should be as comprehensive as needed to meet the quality objectives.

28 The quality system of an organization is designed primarily to meet the internal managerial needs of the organization. It is broader than the requirements of a particular customer, who evaluates only the relevant part of the quality system.

29 For contractual or mandatory quality assessment purposes, demonstration of the implementation of the identified quality system elements may be required.

A.5 quality control: Operational techniques and activities that are used to fulfil requirements for quality.

NOTES

30 Quality control involves operational techniques and activities aimed both at monitoring a process and at eliminating causes of unsatisfactory performance at all stages of the quality loop in order to achieve economic effectiveness.

31 Some quality control and quality assurance actions are interrelated.

A.6 quality assurance: All the planned and systematic activities implemented within the quality system, and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality.

NOTES

32 There are both internal and external purposes for quality assurance:

- a) internal quality assurance: within an organization, quality assurance provides confidence to the management;
- b) external quality assurance: in contractual or other situations, quality assurance provides confidence to the customers or others.

33 Some quality control and quality assurance actions are interrelated.

34 Unless requirements for quality fully reflect the needs of the user, quality assurance may not provide adequate confidence.

A.7 quality improvement: Actions taken throughout the organization to increase the effectiveness and efficiency of activities and processes in order to provide added benefits to both the organization and its customers.

A.8 product: Result of activities or processes.

NOTES

35 A product may include service, hardware, processed materials, software or a combination thereof.

36 A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

37 Product can be either intended (e.g. offering to customers) or unintended (e.g. pollutant or unwanted effects).

A.9 service: Result generated by activities at the interface between the supplier and the customer and

by supplier internal activities to meet the customer needs.

NOTES

38 The supplier or the customer may be represented at the interface by personnel or equipment.

39 Customer activities at the interface with the supplier may be essential to the service delivery.

40 Delivery or use of tangible products may form part of the service delivery.

41 A service may be linked with the manufacture and supply of tangible product.

A.10 customer: Recipient of a product provided by the supplier.

NOTES

42 In a contractual situation, the customer is called the "purchaser".

43 The customer may be, for example, the ultimate consumer, user, beneficiary or purchaser.

44 The customer can be either external or internal to the organization.

A.11 supplier: Organization that provides a product to the customer.

NOTES

45 In a contractual situation, the supplier may be called the "contractor".

46 The supplier may be, for example, the producer, distributor, importer, assembler or service organization.

47 The supplier can be either external or internal to the organization.

A.12 process: Set of interrelated resources and activities which transform inputs into outputs.

NOTE 48 Resources may include personnel, finance, facilities, equipment, techniques and methods.

Annex B

(informative)

Product and process factors

B.1 Purpose

Product and process characteristics are important in the application of the ISO 9000 family. This annex highlights a number of product and process factors that should be considered, for example:

- a) by a supplier's management for quality management purposes, when planning the approach and extent of implementing a quality system element (see 7.1);
- b) by auditors, when planning first-, second- or third-party audits (see 4.9.3);
- c) by supplier and customer jointly when selecting and/or tailoring quality system requirements for a two-party contract (see 8.4).

NOTE 49 In ISO 9000:1987, these factors were given as guidance only for purpose c).

B.2 Factors

a) Complexity of designing

This factor deals with difficulty of designing the product and designing the production and support processes if they have to be designed, or if the design needs periodic change.

b) Maturity and stability of product designs

This factor deals with the extent to which the total product design is known and proven, either by performance testing or field experience.

c) Production process complexity

This factor deals with:

- 1) the availability of proven production processes;
- 2) the need for development of new processes;
- 3) the number and variety of processes required;
- 4) the impact of the process(es) on the performance of the product;
- 5) the need for process control.

d) Product characteristics

This factor deals with the complexity of the product, the number of interrelated characteristics, and whether each characteristic is critical to the performance.

e) Product safety

This factor deals with the risk of the occurrence of failure and the consequences of such a failure.

f) Economics

This factor deals with the economic costs, to both supplier and customer, of the preceding factors weighed against the risk of costs due to nonconformities in the product.

Annex C
(informative)

Proliferation of standards

This ISO 9000 family — in particular, the International Standards for contractual, assessment or certification use (ISO 9001, ISO 9002 and ISO 9003) — is being employed worldwide in many industry/economic sectors for products in all four generic product categories. Various schemes have been developed specific to particular industry/economic sectors.

It is important to distinguish schemes which implement, without change, the ISO 9000 family, from schemes which involve localized versions of these International Standards. If the ISO 9000 family were to become only the nucleus of a proliferation of localized standards derived from, but varying in content and architecture from, the ISO 9000 family, then there would be little worldwide standardization. Once again, there could be worldwide restraint of trade because of the proliferation of standards and inconsistent requirements.

Fortunately, current global marketplace trends are driving many standards users toward strategic recognition that they need and should conform to International Standards. The International Standards in the ISO 9000 family, and the plans for continuing revision, are intended to provide the needed scope, content and flexibility to meet current and emerging marketplace needs in a timely way.

Figure C.1 shows in matrix form which standards implementation activities are recommended in each of four implementation domains, within the quality management and quality assurance arena. Any third-party assessment and certification scheme should operate under procedures that conform fully to all the International Standards, guides and practices as required for mutual international recognition of quality system certification.

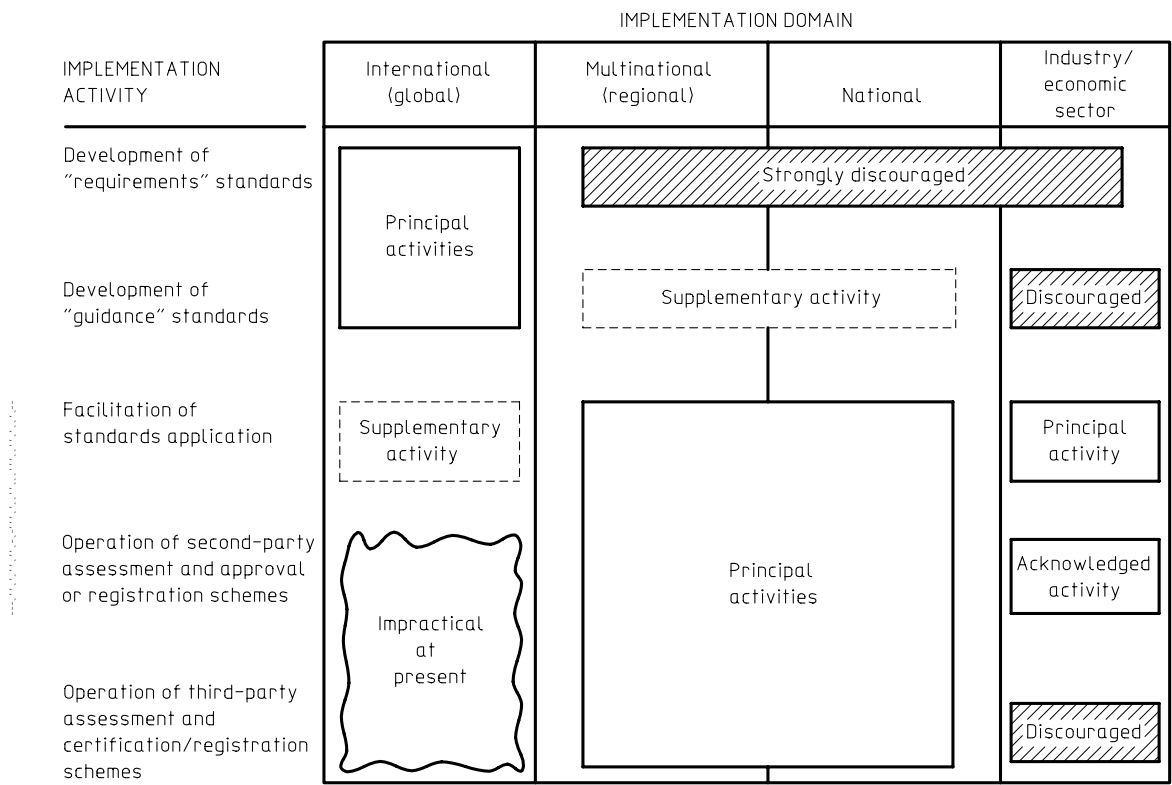


Figure C.1 — Activity matrix for quality assurance standards

Annex D

(informative)

Cross-reference list of clause numbers for corresponding topics

External quality assurance				Clause title in ISO 9001	QM guidance ISO 9004-1	Road map ISO 9000-1
Requirements			Application guide ISO 9000-2			
ISO 9001	ISO 9002	ISO 9003				
4.1 ■	■	○	4.1	Management responsibility	4	4.1; 4.2; 4.3
4.2 ■	■	○	4.2	Quality system	5	4.4; 4.5; 4.8
4.3 ■	■	■	4.3	Contract review	X	8
4.4 ■	X	X	4.4	Design control	8	
4.5 ■	■	■	4.5	Document and data control	5.3; 11.5	
4.6 ■	■	X	4.6	Purchasing	9	
4.7 ■	■	■	4.7	Control of customer-supplied product	X	
4.8 ■	■	○	4.8	Product identification and traceability	11.2	5
4.9 ■	■	X	4.9	Process control	10; 11	4.6; 4.7
4.10 ■	■	○	4.10	Inspection and testing	12	
4.11 ■	■	■	4.11	Control of inspection, measuring and test equipment	13	
4.12 ■	■	■	4.12	Inspection and test status	11.7	
4.13 ■	■	○	4.13	Control of nonconforming product	14	
4.14 ■	■	○	4.14	Corrective and preventive action	15	
4.15 ■	■	■	4.15	Handling, storage, packaging, preservation and delivery	10.4; 16.1; 16.2	
4.16 ■	■	○	4.16	Control of quality records	5.3; 17.2; 17.3	
4.17 ■	■	○	4.17	Internal quality audits	5.4	4.9
4.18 ■	■	○	4.18	Training	18.1	5.4
4.19 ■	■	X	4.19	Servicing	16.4	
4.20 ■	■	○	4.20	Statistical techniques	20	
				Quality economics	6	
				Product safety	19	
				Marketing	7	
Key: ■ = Comprehensive requirement ○ = Less-comprehensive requirement than ISO 9001 and ISO 9002 X = Element not present						

Annex E

(informative)

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1) To be published.

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